

Appl. No. 09/380,310

Art Unit 1616

November 25, 2003

Submission with Request for Continued Examination

REMARKS

Applicants thank the Examiner for her time and for the Interview conducted on November 18, 2003. Applicants believe the Interview has advanced prosecution for the present application.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims.

Previously, claims 1-4, 6-11, 13-18, 20-23, 25, 26 and 28-32 were pending in this application. Herein, claims 1, 6, 8-9, 13, 15-16, 20, 22, 25 and 28-30 have been amended. Claims 31-32 have been canceled and claims 33-42 have been added. Thus, claims 1-4, 6-11, 13-18, 20-23, 25-26, 28-30 and 33-42 are pending in the present application.

No new matter has been added by way of these amendments and new claims because each amendment and new claim is supported by the present specification. For example, the amendments to claim 1, 8, 15, 22, 25 and 28-30 have support throughout the specification, including page 4, line 13, page 7, lines 11-17 and the various Examples. The amendment to claim 15 is further supported at page 6, lines 1-4. The amendments to claims 6, 9, 13, 16 and 20 are obviously for clarification purposes and not narrowing in scope. Thus, Applicants reserve the right to pursue any equivalent feature of the claims. New claims 33-34 have support at page 4, lines 11-20 of the present specification. New claims 35-36 have support at page 3, line 15 and page 4, line 14. New claims 37-38 are supported in the specification at pages 3 and 4. New claims 39-40 are

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supported at page 5, last paragraph. And support for new claims 41-42 can be found at pages 6-7 of the specification. Thus, no new matter has been added.

The amendments to the specification are also editorial in nature and do not add new matter.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 102(b)

Claims 1-3, 6-10, 13-17, 20-22, 25 and 28-32 stand rejected under 35 U.S.C. § 102(b) as anticipated by JP '850 (Aoki et al.; JP Publication Number 07267850 A). Applicants respectfully traverse.

The present invention is directed to a medicinal composition (or a method of treatment or manufacturing) having a basic medicine with an unpleasant taste and an acidic polysaccharide. The unpleasant taste of the medicine is masked by the acidic polysaccharide electrically interacting with the basic, active ingredient, which prevents the basic medicine from dissolving in saliva. In other words, the basic medicine does not separate from the acidic polysaccharide when introduced to

saliva or water due to the acidic polysaccharide electrically interacting with the basic medicine.

The cited JP '850 reference discloses a mixture of a medicine with a water-soluble polymer and wax. The JP '850 composition is fused by melting the wax so that the medicine and a water-soluble polymer are sealed in the matrix of the fused wax (i.e., see all Examples, such as Example 1 at paragraphs [0015]-[0017] that uses a granulator, then heating and cooling the wax-like matter). Thus, JP '850 is a different composition than the present invention, and this reference fails to disclose the interaction of the basic medicine with an acidic polysaccharide as instantly claimed. There is no disclosure in JP '850 of the intimate contact of the claimed ingredients, nor is there any recognition of the electrical interaction that can prevent the unpleasant taste of a basic medicine. Instead, the wax-like matter of JP '850 is the essential ingredient, which also prevents any intimate contact between the ingredients and/or electrical interaction. Specifically, in JP '850, the wax is used to encapsulate the unpleasant tasting medicine and the wax repels water (i.e., interaction with saliva), and is not the same as decreasing the interaction between the medicine itself and the tongue when the composition is in the user's mouth.

Further, the present invention does not use wax as required by the JP '850 reference (which also leads to a different mechanism of action

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of the composition when ingested by the user). Applicants even distinguish the conventional wax methods of masking an unpleasant tasting medicine in the present specification at page 1.

With respect to claims 29, 33 and 35 (reciting "consisting essentially of"), the present invention is patentably distinct for a further reason. JP '850 specifically discloses that the "wax-like matter" prevents the unpleasant taste (*i.e.*, see paragraph [0007]; paragraph [0012] describes various ratios of the "wax-like matter. Also, JP '850 describes that its composition "suppresses the unpleasant taste in the inside of the opening at the time of internal use" (*i.e.*, swallowing), and is "quickly eluted after that in it" (see paragraph [0053]). The JP '850 composition has a different function and mechanism than that of the present invention, whereby the present invention has the acidic polysaccharide electrically interacting with the basic medicine, and the basic medicine has less or no dissolution in the saliva upon ingestion. In fact, Applicants submit that incorporating the wax of JP '850 into the present invention would materially affect the "basic and novel characteristics" of the present invention (*i.e.*, such as electrical interaction between the components). *See PPG Indus., Inc. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-4 (Fed. Cir. 1998). Thus, the present invention is patentable distinct from the JP '850 reference for this additional reason.

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Applicants submit that the present invention is patentably distinct over the cited JP '850 reference. Because "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," the cited JP '850 reference cannot be a basis for a rejection under § 102(b). See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, because of the lack of disclosure of all features (i.e., electrical interaction) as instantly claimed, the rejection in view of JP '850 is overcome. Reconsideration and withdrawal are respectfully requested.

Issues Under 35 U.S.C. § 103(a)

Claims 4, 11, 18, 23 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over JP '850 in view of Matoba et al. '612 (U.S. Patent No. 5,464,612). Applicants respectfully traverse, and reconsideration of the pending claims is respectfully requested.

The Present Invention and Its Advantages

There are many conventional methods and compositions that prevent an unpleasant taste of a medicine, such as those described in the specification (for example, see pages 1-2). These conventional methods/compositions include coating a granulated agent with a water-soluble film (as described in JP-A 4-282312), and melting a waxy substance

in order to disperse and solidify the medicine (as described in the cited JP '850 reference). These methods do have drawbacks, also described in the specification (page 2, lines 9-14), including compromises of quality and a reduced effectiveness of the medicine itself.

In contrast, the present invention is directed to oral medicine compositions that effectively reduce and prevent the unpleasant taste of basic medicines (*i.e.*, donepezil hydrochloride). The present invention is further directed to methods for preventing the unpleasant taste of the basic medicines that include the mentioned oral medicine compositions, and a process of making such a composition. Specifically, the claimed oral medicine compositions comprise an acidic polysaccharide and the basic medicine, where the acidic polysaccharide is mixed or blended with the basic medicine to effectively avoid the unpleasant taste of the medicine. Upon swallowing, the bonding rate between the basic medicine and the tongue is reduced when the saliva starts to dissolve the pharmaceutical composition.

However, the prior art fails to disclose the claimed combinations and methods comprising the acidic polysaccharide and basic medicine according to the present invention and present claims.

Distinctions over the Combination of JP '850 and Matoba '612

The cited combination of JP '850 and Matoba '612 fails to disclose all features as instantly claimed because neither reference, even when

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they are combined (whether proper or not), discloses the combination of the acidic polysaccharide with the basic medicine and the electrical interaction as instantly claimed. Each reference does not account for the deficiencies of each other, and one of ordinary skill in the art cannot account for these deficiencies either upon a reading of these references.

Matoba '612 is generally directed to clad powdery and granular preparations of medically active ingredients and ion exchangers (see Abstract). The disclosed coating composition includes a list of water-soluble polymers, water-insoluble polymers, acid-soluble polymers, and enteric polymers (see Col. 6, lines 18-25).

However, the primary reference of JP '850 not only fails to disclose the elements of the present invention, the additional disclosure of Matoba '612 fails to add the necessary disclosure to motivate one of ordinary skill in the art to arrive at the present invention of a medicinal composition made up of a basic medicine and an acidic polysaccharide. There is even no disclosure or recognition of the bonding interaction and/or intimate contact as instantly claimed. Thus, Matoba '612 fails to account for the deficiencies of the primary reference of JP '850, and the cited combination of references fails to disclose all features as instantly claimed. As such, Applicants respectfully submit that not all requirements for a *prima facie* case of

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obviousness has been formed. Accordingly, Applicants request that the instant rejection be withdrawn.

Applicants respectfully submit that the present invention is patentably distinct from the cited combination of references for the reasons stated above. Therefore, reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

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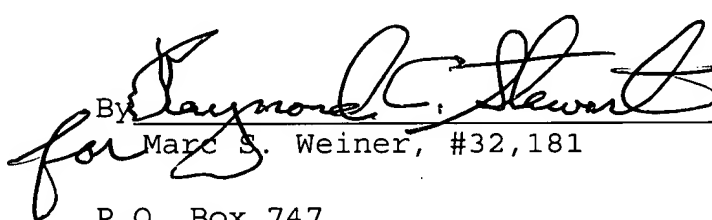
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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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